K092607
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Bard Medical Division
C. R. Bard, Inc
8195 Industrial Blvd.
Covington, GA 30014

NOV 20 2009

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc. Bard Medical Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John Knorpp
Contact Person's Telephone Number:	770-784-6316

B. DEVICE NAME:

Trade Name(s):	Ajust™ Adjustable Single Incision Sling
Common/Usual Name:	Urethral Sling; Surgical Mesh
Classification Names:	PAH – Mesh, Surgical, Polymeric;
CFR Reference:	21 CFR 878.3300, Surgical mesh

C. PREDICATE DEVICES:

Trade Name(s):
- Align® Urethral Support System
- Tissue Fixation System Sling
- MiniArc™ Sling System
- IVS Tunneller™ System
- Elevate™ Prolapse Repair System

D. DEVICE DESCRIPTION:

The Ajust™ Adjustable Single Incision Sling is for use in urological and gynecological procedures for the treatment of stress urinary incontinence in women. The sling is secured in the patient's tissue using two soft tissue anchors. An introducer is used to insert the anchors using a similar approach to a transobturator sling. The implant design allows independent adjustment of the mesh relative to the anchors, after which, the mesh is secured in place using a small locking mechanism.

E. INTENDED USE:

The Ajust™ Adjustable Single Incision Sling is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The principles of operation and fundamental scientific technology are equivalent to the predicate devices

G. PERFORMANCE DATA SUMMARY:

Bench performance testing, pre-clinical studies and clinical data were used to determine equivalence of the Ajust™ Adjustable Single Incision Sling to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C. R. Bard, Inc.
% Bard Medical Division
John C. Knorpp, RAC
Director, Regulatory Affairs
8195 Industrial Boulevard
COVINGTON GA 30014

SEP 28 2012

Re: K092607
Trade/Device Name: Ajust™ Adjustable Single Incision Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: August 21, 2009
Received: August 25, 2009

Dear Mr. Knorpp:

This letter corrects our substantially equivalent letter of November 20, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

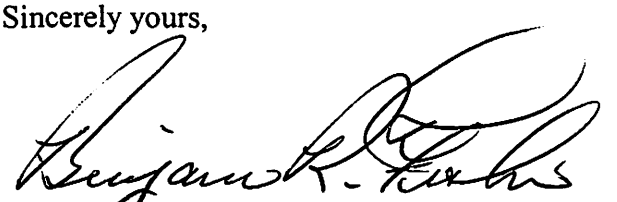
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092607

1.3 Indications for Use Statement

510(k) Number (if known): K092607

Device Name: Ajust™ Adjustable Single Incision Sling

Indications for Use:

The Ajust™ Adjustable Single Incision Sling is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092607